

1 CLAIMS

2 What is claimed is:

3  
4 Claim 1. A biopolymer marker selected from the group  
5 consisting of ~~sequence ID (K) ALVQOMEQLR(Q),~~  
6 ~~(K) LVPFATELHER(L), (R) RVEPYGENFNK(A), (R) LEPYADQLR(T)~~ or  
7 at least one analyte thereof useful in indicating at least  
8 one particular disease state.

9  
10 Claim 2. The biopolymer marker of claim 1 wherein  
11 said disease state is predictive of Type II diabetes.

12  
13 Claim 3. A method for evidencing and categorizing at  
14 least one disease state comprising:

15 obtaining a sample from a patient;

16 conducting mass spectrometric analysis on said  
17 sample;

18 evidencing and categorizing at least one biopolymer  
19 marker sequence or analyte thereof isolated from said  
20 sample; and,

21 comparing said at least one isolated biopolymer  
22 marker sequence or analyte thereof to the biopolymer  
23 marker sequence as set forth in claim 1;

24 wherein correlation of said isolated biopolymer

1 marker and said biopolymer marker sequence as set forth in  
2 claim 1 evidences and categorizes said at least one  
3 disease state.

4  
5 Claim 4. The method of claim 3, wherein said step  
6 of evidencing and categorizing is particularly directed to  
7 biopolymer markers or analytes thereof linked to at least  
8 one risk of disease development of said patient.

9  
10 Claim 5. The method of claim 3, wherein said step  
11 of evidencing and categorizing is particularly directed to  
12 biopolymer markers or analytes thereof related to the  
13 existence of a particular disease state.

14  
15 Claim 6. The method of claim 3, wherein the sample  
16 is an unfractionated body fluid or a tissue sample.

17  
18 Claim 7. The method of claim 3, wherein said sample  
19 is at least one of the group consisting of blood, blood  
20 products, urine, saliva, cerebrospinal fluid, and lymph.

21  
22 Claim 8. The method of claim 3, wherein said mass  
23 spectrometric analysis is selected from the group  
24 consisting of Surface Enhanced Laser Desorption Ionization

1 (SELDI) mass spectrometry (MS), Maldi Qq TOF, MS/MS,  
2 TOF-TOF, and ESI-Q-TOF or an ION-TRAP.

3  
4 Claim 9. The method of claim 3, wherein said  
5 patient is a human.

6  
7 Claim 10. A diagnostic assay kit for determining  
8 the presence of the biopolymer marker or analyte thereof  
9 of claim 1 comprising:

10 at least one biochemical material which is capable of  
11 specifically binding with a biomolecule which includes at  
12 least said biopolymer marker or analyte thereof, and

13 means for determining binding between said  
14 biochemical material and said biomolecule;

15 whereby at least one analysis to determine a presence  
16 of a marker, analyte thereof, or a biochemical material  
17 specific thereto, is carried out on a sample.

18  
19 Claim 11. The diagnostic assay kit of claim 10,  
20 wherein said biochemical material or biomolecule is  
21 immobilized on a solid support.

1 Claim 12. The diagnostic assay kit of claim 10  
2 including:

3 at least one labeled biochemical material.  
4

5 Claim 13. The diagnostic assay kit of claim 10,  
6 wherein said biochemical material is an antibody.  
7

8 Claim 14. The diagnostic assay kit of claim 12,  
9 wherein said labeled biochemical material is an antibody.  
10

11 Claim 15. The diagnostic assay kit of claim 10,  
12 wherein the sample is an unfractionated body fluid or a  
13 tissue sample.  
14

15 Claim 16. The diagnostic assay kit of claim 10,  
16 wherein said sample is at least one of the group  
17 consisting of blood, blood products, urine, saliva,  
18 cerebrospinal fluid, and lymph.  
19

20 Claim 17. The diagnostic assay kit of claim 10,  
21 wherein said biochemical material is at least one  
22 monoclonal antibody specific therefore.  
23

24 Claim 18. A kit for diagnosing, determining risk-

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1 assessment, and identifying therapeutic avenues related to  
2 a disease state comprising:

3 at least one biochemical material which is capable of  
4 specifically binding with a biomolecule which includes at  
5 least one biopolymer marker selected from the group

6 consisting of <sup>SEQ ID NO. 1</sup> sequence ID (K)ALVQOMEQLR(Q),  
7 <sup>SEQ ID NO. 2</sup> (K)LVPTATELHER(L) <sup>SEQ ID NO. 3</sup> (R)RVEPYGENFNK(A), <sup>SEQ ID NO. 4</sup> (R)LEPYADQLR(T) or at

8 least one analyte thereof related to said disease state;  
9 and

10 means for determining binding between said  
11 biochemical material and said biomolecule;

12 whereby at least one analysis to determine a presence  
13 of a marker, analyte thereof, or a biochemical material  
14 specific thereto, is carried out on a sample.

15  
16 Claim 19. The kit of claim 18, wherein said  
17 biochemical material or biomolecule is immobilized on a  
18 solid support.

19  
20 Claim 20. The kit of claim 18 including:  
21 at least one labeled biochemical material.

22  
23 Claim 21. The kit of claim 18, wherein said  
24 biochemical material is an antibody.

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1           Claim 22.    The kit of claim 20, wherein said labeled  
2 biochemical material is an antibody.

3  
4           Claim 23.    The kit of claim 18, wherein the sample is  
5 an unfractionated body fluid or a tissue sample.

6  
7           Claim 24.    The kit of claim 18, wherein said sample  
8 is at least one of the group consisting of blood, blood  
9 products, urine, saliva, cerebrospinal fluid, and lymph.

10  
11          Claim 25.    The kit of claim 18, wherein said  
12 biochemical material is at least one monoclonal antibody  
13 specific therefore.

14  
15          Claim 26.    The kit of claim 18, wherein said  
16 diagnosing, determining risk assessment, and identifying  
17 therapeutic avenues is carried out on a single sample.

18  
19          Claim 27.    The kit of claim 18, wherein said  
20 diagnosing, determining risk assessment, and identifying  
21 therapeutic avenues is carried out on multiple samples  
22 such that at least one analysis is carried out on a first  
23 sample and at least another analysis is carried out on a  
24 second sample.

1 Claim 28. The kit of claim 27, wherein said first  
2 and second samples are obtained at different time periods.

3  
4 Claim 29. Polyclonal antibodies produced against a  
5 marker sequence ID selected from the group consisting of  
6 ~~sequence ID~~ <sup>SEQ ID NO:1</sup> (K)ALVQOMEQLR(Q), <sup>SEQ ID NO:2</sup> (K)LVPFATELHER(L),  
7 <sup>SEQ ID NO:3</sup> (R)RVEPYGENFNK(A), <sup>SEQ ID NO:4</sup> (R)LEPYADQLR(T) or at least one analyte  
8 thereof in at least one animal host.

9  
10 Claim 30. An antibody that specifically binds a  
11 biopolymer including a marker selected from the group  
12 consisting of ~~sequence ID~~ <sup>SEQ ID NO:1</sup> (K)ALVQOMEQLR(Q),  
13 <sup>SEQ ID NO:2</sup> (K)LVPFATELHER(L), <sup>SEQ ID NO:3</sup> (R)RVEPYGENFNK(A), <sup>SEQ ID NO:4</sup> (R)LEPYADQLR(T) or at  
14 least one analyte thereof.

15  
16 Claim 31. The antibody of claim 30 that is a  
17 monoclonal antibody.

18  
19 Claim 32. The antibody of claim 30 that is a  
20 polyclonal antibody.

21  
22 Claim 33. A process for identifying therapeutic  
23 avenues related to a disease state comprising:  
24 conducting an analysis as provided by the kit of

1 claim 18; and

2 interacting with a biopolymer selected from the group

3 consisting of <sup>SEQ ID NO: 1</sup> sequence ID (K)ALVQOMEQLR(Q),

4 <sup>SEQ ID NO: 2</sup> (K)LVPFATELHER(L), <sup>SEQ ID NO: 3</sup> (R)RVEPYGENFNK(A), <sup>SEQ ID NO: 4</sup> (R)LEPYADQLR(T) or

5 at least one analyte thereof;

6 whereby therapeutic avenues are developed.

7  
8 Claim 34. The process for identifying therapeutic

9 avenues related to a disease state in accordance with

10 claim 33, wherein said therapeutic avenues regulate the

11 presence or absence of the biopolymer selected from the

12 group consisting of <sup>SEQ ID NO: 1</sup> sequence ID (K)ALVQOMEQLR(Q),

13 <sup>SEQ ID NO: 2</sup> (K)LVPFATELHER(L), <sup>SEQ ID NO: 3</sup> (R)RVEPYGENFNK(A), <sup>SEQ ID NO: 4</sup> (R)LEPYADQLR(T) or

14 at least one analyte thereof.

15  
16 Claim 35. The process for identifying therapeutic

17 avenues related to a disease state in accordance with

18 claim 33, wherein said therapeutic avenues developed

19 include at least one avenue selected from a group

20 consisting of 1)utilization and recognition of said

21 biopolymer markers, variants or moieties thereof as direct

22 therapeutic modalities; either alone or in conjunction

23 with an effective amount of a pharmaceutically effective

24 carrier; 2)validation of therapeutic modalities or disease



1 preventative agents as a function of biopolymer marker  
 2 presence or concentration; 3) treatment or prevention of a  
 3 disease state by formation of disease intervention  
 4 modalities; 4) use of biopolymer markers or moieties  
 5 thereof as a means of elucidating therapeutically viable  
 6 agents, 5) instigation of a therapeutic immunological  
 7 response; and 6) synthesis of molecular structures related  
 8 to said biopolymer markers, moieties or variants thereof  
 9 which are constructed and arranged to therapeutically  
 10 intervene in said disease state.

11  
 12 Claim 36. The process for identifying therapeutic  
 13 avenues related to a disease state in accordance with  
 14 claim 35, wherein said treatment or prevention of a  
 15 disease state by formation of disease intervention  
 16 modalities is the formation of biopolymer/ligand  
 17 conjugates which intervene at receptor sites to prevent,  
 18 delay or reverse a disease process.

19  
 20 Claim 37. The ~~process~~ for identifying therapeutic  
 21 avenues related to a disease state in accordance with  
 22 claim 35, wherein said means of elucidating  
 23 therapeutically viable agents includes use of a  
 24 bacteriophage peptide display library or a bacteriophage

1 antibody library.

2

3 Claim 38. A process for regulating a disease state

4 by controlling the presence or absence of a biopolymer

5 selected from the group consisting of ~~sequence ID~~

6 ~~(K)ALVQOMEQLR(Q), (K)LVPFATELHER(L), (R)RVEPYGENENK(A),~~

7 (R)LEPYADQLR(T) or at least one analyte thereof.

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